

10-31-07

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PTO/SB/21 (04-07)

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|---|----------------------|-------------------------|--------------------|
| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 09/827,266 | |
| | Filing Date | April 5, 2001 | |
| | First Named Inventor | James G. Skakoon et al. | |
| | Art Unit | 3737 | |
| | Examiner Name | Amanda L. Lauritzen | |
| Total Number of Pages in This Submission | | Attorney Docket Number | 50741-000005/US/01 |

| ENCLOSURES (check all that apply) | | |
|--|---|---|
| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Request for Continued Examination (1 page) <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Form 1449 (2 pages); 6 Foreign Art References; 9 Non-Patent References; and Return Receipt Postcard. |
| Remarks | | The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed. |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | | | |
|--|----------------------------------|----------|--------|
| Firm Name | Harness, Dickey & Pierce, P.L.C. | | |
| Signature | | | |
| Printed name | Richard W. Warner | | |
| Date | October 30, 2007 | Reg. No. | 38,043 |

| CERTIFICATE OF TRANSMISSION/MAILING | | | |
|---|-------------------|------------------------|------------------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. | | | |
| Typed or printed name | Richard W. Warner | Express Mail Label No. | EM 062951765 |
| Signature | | Date | October 30, 2007 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 09/827,266
Filing Date: April 5, 2001
Applicant: James G. Skakoon
Group Art Unit: 3737
Examiner: A. L. Lauritzen
Title: MEDICAL DEVICE INTRODUCER
Attorney Docket: 5074I-000005/US/01

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. COPIES

A. ☒ Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office; (iii) each unpublished U.S. application listed below in Section IV (i.e., including the specification, claims, and any drawing of the application, or that portion of the application which caused it to be listed, including any claims directed to that portion), except for such applications filed on or after June 30, 2003, pursuant to the Waiver of the Copy Requirement in 37 C.F.R. 1.98 (OG Notice dated October 19, 2004); and (iv) all other information or that portion which caused it to be listed.

B. ☒ Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

10/370,090

11/381,647

11/381,659

11/738,893

U.S. Filing Date

February 20, 2003

May 4, 2006

May 4, 2006

April 23, 2007

C. ☐ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search report are listed on the attached Form 1449 for consideration by the Examiner and for listing on any patent resulting from this application. If the International Search report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g).)

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. ☒ Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. ☒ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. ☐ See the attached foreign patent office communication from a counterpart foreign application:

2. ☐ English translations are provided:

3. ☒ Other:

An English abstract has been provided for German Patent DE19808220.

An English abstract has been provided for German Patent DE19820808.

An English abstract has been provided for German Patent DE19826078.

German Patent DE 296 12 100 appears to disclose an instrument with a bore through at least a portion of a rod.

An English abstract has been provided for WIPO Patent WO97/21380.

An English abstract has been provided for WIPO Patent WO98/17191.

C. ☐ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. ☒ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does (do) not waive the confidentiality provisions of 35 U.S.C. § 122.

| <u>Serial No.</u> | <u>Filing Date</u> | <u>Inventor(s)</u> |
|-------------------|--------------------|--------------------|
| 09/828,451 | April 6, 2001 | Skakoon et al. |
| 11/768,065 | June 25, 2007 | Murdock et al. |
| 11/768,077 | June 25, 2007 | Murdock et al. |
| 11/768,554 | June 26, 2007 | Mazzocchi et al. |
| 11/768,741 | June 26, 2007 | Mazzocchi et al. |
| 11/768,760 | June 26, 2007 | Mazzocchi et al. |
| 10/894,958 | July 20, 2004 | Parmer et al. |
| 11/005,907 | December 6, 2004 | Skakoon et al. |

V. THIS IDS IS BEING FILED UNDER

A. ☒ **37 C.F.R. § 1.97(b):** (check only one box)

1. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.

2. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.

3. ☐ before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first

Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. ☒ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. ☐ **37 C.F.R. § 1.97(c):** (check only one box)

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. ☐ See the certification below. No fee is required.

C. ☐ **37 C.F.R. § 1.97(d):**

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. ☐ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. ☐ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. 1.704(d) below in section VII, if applicable; or

B. ☐ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. ☐ some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 C.F.R. 1.704(d)

The undersigned hereby states that:

☐ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box, if applicable)

A. ☐ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. ☐ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-identified fee. A duplicate copy of this paper is attached.

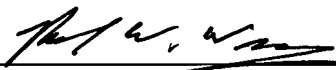
Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Respectfully submitted,

Dated: October 30, 2007

By: 
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